MedSun Newsletter #32, January 2009

Articles

FDA Announces Class I Recalls of Two Unapproved Devices

FDA Press Release

The U.S. Food and Drug Administration (FDA) announced a Class 1 recall today for two unapproved and uncleared devices whose manufacturers claimed could treat various medical conditions. A Class 1 recall means that there is a reasonable probability that the use of a device will cause adverse health consequences or death.

The manufacturers, VIBE Technologies of Greeley, Colo., and Nebion LLC of Los Angeles, Calif., claimed their devices treated conditions ranging from cancer to migraines. The FDA is concerned that based upon the original health claims made by the company, patients may forgo approved therapies, and that this could result in more severe illness or death.

"These recalls underscore the importance of taking action against manufacturers who make false medical claims for their devices," said Daniel G. Schultz, M.D., director of the FDA's Center for Devices and Radiological Health. "One of the FDA's primary responsibilities is protecting consumers from harm that can be caused by manufacturers who try to sidestep the approval and clearance process."

Vibrational Integrated Bio-photonic Energizer device

On April 11, 2008, the FDA issued a warning letter to VIBE Technologies stating that the agency's November 2007 inspection of the facility showed that the company had not obtained FDA marketing approval or clearance for the Vibrational Integrated Bio-photonic Energizer (VIBE device), which claims to treat cancer, infections, and depression. The FDA also cited the company for substantial deviations from the current Good Manufacturing Practice/Quality System regulation.

VIBE Technologies initiated a recall of 840 VIBE devices in an April 3, 2008, letter sent to users. VIBE Technologies agreed to stop promoting and marketing the VIBE device, and will contact all those who had purchased it to ensure no other unsubstantiated medical claims are being made. The FDA has requested that the company update its recall notices to state that the VIBE device is not intended for the treatment of any diseases or medical conditions.

The FDA is aware of information that suggests that the VIBE device has been used in cancer patients. There is one death that occurred in a patient who used this device. However, FDA has not verified that there is any association between the death and the VIBE device.

HLX8 device

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In June 2008 FDA inspected Nebion, LLC, which revealed that the company had not obtained FDA marketing approval or clearance for the HLX8 device, which claims to treat cancer, migraines, arthritis, and ruptured discs. The inspection also uncovered substantial deviations from the Current Good Manufacturing Practice/Quality System regulation.

Nebion recalled eight HLX8 devices on July 2, 2008, and notified their customers to stop using the devices immediately and to contact Nebion for their retrieval.
Nebion's first recall letter did not address the potential risks associated with the HLX8 device, but the company has recently notified FDA that they will issue a second letter that identifies potential health hazards. The FDA has not received any reports of injuries or deaths linked with the HLX8 device.

Under federal law, products that claim to diagnose a disease or condition, cure, mitigate, treat or prevent disease, or that are intended to affect the structure or function of the body are devices subject to FDA jurisdiction and may require FDA approval or clearance prior to marketing. Premarket approval is the most stringent type of FDA device review and is for devices with a high level of risk, such as those that support or sustain human life. FDA clearance is for lower risk devices that are shown to be as safe and effective as a similar device already on the market.

Neither VIBE Technologies nor Nebion has demonstrated to the FDA that their device is safe and effective at curing or treating diseases as claimed.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.
•Online: www.fda.gov/MedWatch/report.htm
•Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
•Fax: (800) FDA-0178
•Phone: (800) FDA-1088
Health care professionals and patients can obtain further details about the recalls from VIBE Technologies at 970-356-9594 or Nebion LLC, at 310-215-6400.

Additional Information:

FDA Announces Class I Recalls of Two Unapproved Devices. FDA Press Release. December 15, 2008.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116990.htm
7

Class 1 Recall: VIBE Technologies, Vibrational Integrated Bio-photonic Energizer (VIBE) Machine Multi-Frequency Field Generator. FDA Medical Device Safety Website. November 3, 2008.

http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062296.htm[8]

Class 1 Recall: Nebion, LLC HLX-8 Magnetic Resonance Device. FDA Medical Device Safety Website. October 3, 2008.
http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062310.htm[9]

The Guidelines for Disinfection Sterilization in Healthcare Facilities

By William A. Rutala PhD and David J. Weber
The Centers for Disease Control (CDC)

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization. Failure to comply with scientifically-based guidelines has led to numerous outbreaks. This guideline presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes; the approach is based on well-designed studies assessing the efficacy (through laboratory investigations) and effectiveness (through clinical studies) of disinfection and sterilization procedures

Additional Information:

The Guidelines for Disinfection Sterilization in Healthcare Facilities. Rutala, William; Weber, David. The Centers for Disease Control. 2008.
[11]

http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf[12]

Venous Air Emboli and Automatic Contrast Media Injectors

Several reports have been submitted to PA-PSRS in which intravascular air emboli occurred with the use of automatic contrast media injectors during CT scans. If the device is not at fault there are several things that can be done to address the risk of air emboli with automatic contrast injectors. These include adequate training for healthcare professionals, having contrast injector procedures readily available to staff, and developing protocols to promote compliance.

You may read a recent MedSun report with this device in the clinical environment online available under Additional Information below

Additional Information:

Venous Air Emboli and Automatic Contrast Media Injectors. Pennsylvania Patient Safety Authority – Patient Safety Reporting System (PSRS) Patient Safety Advisory. Volume 1,

Number 4. December 2004.
[14]

http://www.psa.state.pa.us/psa/lib/psa/advisories/v1n4december2004/dec2004vol14_article_i_venous_air_emboli.pdf[15]

MedSun report – Stellant injector contrast – November 10, 2008
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/medsun_details.cfm?ID=%25%22%2DC6%26OP%20%0A[16]

LabNet

Reducing Errors in the Clinical Laboratory: A Lean Production System Approach

By David A. Novis, MD
LabMedicine

Performance benchmarks by clinical practices allow us to deduce which of those practices we believe to be "best". But often times benchmarking encourages intervention retroactively. To prevent errors in the lab, a more proactive approach to error prevention is necessary.

Additional Information:

Reducing Errors in the Clinical Laboratory: A Lean Production System Approach. By David A. Novis, MD. LabMedicine. September 2008.
[18]

http://www.davidnovis.com/docs/0908_Novis_Feature.pdf[19]

New Device Approval - COBAS TaqMan HCV Test For Use With the COBAS AmpliPrep Instrument and the COBAS TaqMan Analyzer or the COBAS TaqMan 48 Analyzer - P060030

FDA Center for Devices and Radiological Health (CDRH) Consumer Health Information Website

FDA has recently approved the COBAS TaqMan HCV Test. This laboratory test measures the amount of hepatitis C viral RNA in a patient's blood and is used to evaluate the treatment of an individual infected with the hepatitis C virus.

Additional Information:

COBAS TaqMan HCV Test. FDA Center for Devices and Radiological Health (CDRH) Consumer Health Information Website. October 30, 2008. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm073968.htm[21]

HomeNet

FDA Recall Notice: Animas Corporation Battery Caps Used with the OneTouch Ping System

FDA Website

Animas Corporation and FDA informed consumers and healthcare professionals of a nationwide recall of battery caps used with the OneTouch Ping System, Animas 2020 Insulin Pump, Animas IR1200 Insulin Pump, and Animas IR1250 Insulin Pump. The battery caps used with the above infusion pumps were manufactured from June 1, 2008 through July 31, 2008, and were distributed from June 16, 2008 through August 1, 2008.

There may be an intermittent loss of contact between the battery cap and the battery compartment in the pump which may result in the device resetting. This can cause the device to stop administering insulin, which could result in an excess level of glucose in the blood (hyperglycemia). Additionally, this failure may lead to user confusion in the amount of insulin administered, contributing to errors in future doses, which may result in lower than normal level of glucose in the blood (hypoglycemia). Healthcare professionals are advised to ensure that their patients replace the battery cap on their insulin pump.

Additional Information:

Class 1 Recall: Animas Corporation, Battery Caps Used with the OneTouch Ping System, Animas 2020 Insulin Pump, Animas IR1200 Insulin Pump, and Animas IR1250 Insulin Pump. FDA Medical Device Recalls Website. November 20, 2008. http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062308.htm[23]

Fire Safety and Oxygen: A Patient Guide

American College of Clinical Engineering (ACCE)

We want to draw your attention to a patient safety brochure entitled, "Fire Safety & Oxygen: A Patient Guide," published by the ACCE Healthcare Technology Foundation. It is available as a free download in both English and Spanish and it may be reproduced. A limited numbers of printed copies are also available upon request. Please take a look!

Additional Information:

Fire Safety and Oxygen: A Patient Guide. American College of Clinical Engineering (ACCE). 2008.
[25]

http://www.accefoundation.org/documents/HomeDevice_Oxygen.pdf[26]

Fire Safety and Oxygen: A Patient Guide (in Spanish)
[27]

http://www.accefoundation.org/documents/Home%20Medical%20Device%20Spanish.pdf[28]

Highlighted MedSun Reports

Highlighted Reports

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period October 1 through October 31. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

NEUROLOGY

Device 1: Catheter, Thermal Regulation
Manufacturer: Alsius Corporation
Brand: Cool Line
Model #: 601038-001
Lot #: 19569
Cat #: CL-2295

Device 2: Temperature Control Unit
Manufacturer: Alsius Corporation
Brand: Coolgard 3000
Model #: CoolGard 3000

Problem:
Catheter inserted over a pre-existing line in the Left Subclavian for fever management. Clinician recalls a "one-pass slide in without obstruction" during insertion. The unit appeared to have functioned properly over the next 48 hour period. No leakage or blood noted in line. Pinwheel on the startup kit was rotating indicating flow was checked and

operational. No alarms present and no saline was missing from set during this period. Per RN, machine audible alarm sounded and screen read "air in line" four days later. RN noted only 30 cc of saline remaining in the neoprene wrapped bag of 500 cc saline, with lots of air noted in the saline bag. The bag was primed with 250 cc of the 500 cc of saline upon set-up, with a remaining 220- 250 cc of saline visible. There was no change in vital signs other than the patient's temperature began to rise. The sutures were removed and upon attempted removal of the catheter the clinician met with resistance. A vascular surgeon was consulted who removed the catheter in the operating room. The balloon was ruptured and it is unclear at this time when the rupture occurred.

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Manufacturer response for Catheter, Thermal Regulation, Cool Line, and Temperature Control Unit, CoolGard 3000

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Requested catheter by sales representative came in and investigated unit prior to facility notification of either Biomed or Risk management. Vendor states that memory had been wiped out and that there was no error codes present.

CLINICAL CHEMISTRY

Device 1: Analyzer, Blood Glucose, Point Of Care
Manuf: Roche Diagnostics Corporation
Brand: Accucheck Inform Machine

Device 2: Control Solution, Blood Glucose Analyzer
Manufacturer: Roche Diagnostics Corporation
Brand: Accucheck Level 1Solution
Lot #: 73320
Cat #: 2030365

Device 3: Control Solution, Blood Glucose Analyzer
Manufacturer: Roche Diagnostics Corporation
Brand: Control Solution Level 2
Lot #: 73320
Cat #: 2030365

Device 4: Test Strips, Blood Glucose Analyzer
Manufacturer: Roche Diagnostics Corporation
Brand: Accucheck Comfort Curve Strips
Lot #: 550645
Cat #: 2030365

Problem:
This patient arrived to the ED via wheelchair with a family member. He was triaged with an initial complaint of a sore throat, nausea, and vomiting for a couple of days. After triage, the patient was sent to the waiting room. The nurse went to the waiting room to

bring the patient back. They found the patient laying on the floor in the waiting room and was arousable, but lethargic. They questioned the family member regarding the patient's current status and why he was laying on the floor. The patient was not feeling well and he was then brought back to the room. After the initial treatment was done (monitor, IV, blood drawn, etc), an initial blood glucose check was done. The RN said that before she could complete the blood glucose check the controls had to be done, which she completed. According to the documentation the blood glucose check read too low to register and the test was repeated. The repeat blood glucose check also read too low to register. The physicians were informed of the results. Two ampoules of Dextrose 5% were ordered and given. IV fluids of Dextrose 5% with half normal saline was started. Approximately 35 minutes later, the lab reported and documented that the patient's serum glucose result was 1284. The doctor was informed and new orders for an insulin drip, and the IV fluid was changed to normal saline. Another blood glucose check was also done at this time, and the results were high. In the blood glucose history, the control reading and the high reading were present. However, the two low readings were not there. The patient was admitted to the ICU; he was diagnosed as a new diabetic and discharged home six days later.

Device: Test Strip, Blood Glucose
Manufacturer: Lifescan, Inc.
Brand: Sure Step Pro
Lot #: 2860185 008
Cat #: 010-797

Problem:
The defective test strips have a black band on the same side of the test strip that has the pink application square. A black band should not be present on that side of the test strip. The test pad on the defective test strips will either be missing or very loosely attached. The confirmation dot on the back of the test strip may also be off center. Lifescan has been notified and has acknowledged the problem. As of the end of September there has been no resolution.
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Manufacturer response for Test Strip, Blood Glucose, Sure Step Pro
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A voice mail was left for the rep. We have not heard back from them yet.

ANESTHESIOLOGY

Device: Ventilator, Cpap
Manufacturer: ResMed Corporation
Brand: Vpap Iii St
Model #: VPAP ST III
Problem:
The VPAP III ST device was working as intended at the beginning of the testing. The technician turned off the device to remove excess condensation from the air tubing before

changing the mode of therapy delivered. The technologist is certain the VPAP III was turned back on. As testing continued, the patient was not responding to changes made to the device via the remote control. The technician checked with the patient and the patient confirmed that he/she was receiving pressure via the device. During this time, the device was providing a flow signal to the polysomnogram (PSG) system. The technician further investigated and discovered that the patient was wearing the CPAP mask, but the ResMed VPAP machine was turned off. (It can not be ascertained by available video if the VPAP III was manually turned off/on or if this was a system anomaly). Turning the machine back on corrected the problem. This issue was discovered 2 1/2 hours after the occurrence. Patient had temporary respiratory distress that required no intervention. Follow up: The CPAP flow signal was still visible on the PSG display even though there wasn't any pressure being delivered via the flow generator. There wasn't any indication on the ResControl remote that the flow generator was not functioning (the device is not in SmartStart mode-this feature is turned off).

GENERAL HOSPITAL

Device: Pump, Pca
Manufacturer: B Braun Medical Inc.
Brand: Patient Controlled Analgesia Pump
Lot #: 3509010b

Problem:
Pt. complained of not getting relief from PCA medication. RN realized that most of the medication was still in the bag. Further assessment revealed that the PCA button was not working (i.e. when pushed pt did not receive bolus). Biomedical engineering tested the pump and identified a broken cable as the source of the problem. This has been a frequent problem with these pumps. Biomed believes the cable should be designed to be more flexible. We are also reminding our staff not to tightly wrap the cords for storage.

Device: Pump, Iv
Manufacturer: Hospira Global Medical Affairs
Brand: Symbiq
Other #: 208144

Problem:
The Symbiq pump began infusing at 11:35. At approximately 1:04 the pump alarmed with malfunction alarm S321 Motor Error, Error Subgroup 9, Code: pump bolus overshoot, Urgency High, Alarm ID 109, Generic Arg 1: 814, Arg 2: 0, Arg 3: 0, Arg 4:0. The alarm was acknowledged and the cassette was manually ejected. The infusion was stopped and the pump powered down. I have now documented the same malfunction alarm and error on four different pumps all of the same make and model. This device has been on the market for approximately 1 year. I have registered this with the OEM and have returned it for analysis.

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Device: Stopcock, Iv
Manufacturer: Teleflex Medical
Brand: Arrow Walrus

Problem:
Stopcock cracked on UAC, patient lost 15-20 ml of blood. Monitor alarmed and baby checked, leak found. Nurse blocked stopcock to prevent more leaking - stopcock changed. Baby given transfusion of PRBC's.

Device: Syringe
Manufacturer: Becton Dickinson
Brand: BD
Lot #: 8151405
Cat #: REF 309604
Other #: (01)00382903096046

Problem:
The RN was adjusting the rate of the drug because the BP was not responding to meds. Infusion rate programmed at 0.2 ml per hour. Three and half hours later after the start of infusion, the line was clamped. The syringe was taken out of the pump and examined. Apparently 5 ml of medication leaked out during the three and half hours. She then noticed about one foot of the tubing had air in the line, and syringe was mostly full of air. RN clamped and disconnected the tubing. Since syringe pumps do have an air in line detector; if not seen, a huge air embolis would almost certainly have been injected into the infant.

Device: Stretcher
Manufacturer: STERIS Corporation
Brand: Multi-purpose Stretchers
Cat #: 462DPAST

Problem:
When the stretcher’s side rails are lowered, the bottom of the side rail hits the regulator valve knob on the oxygen cylinder that is located under the stretcher. This action creates an unsafe mechanical shock hazard for the cylinder. Compressed gas cylinders and their regulators are supposed to be located so that they are protected at all times from being struck by other objects.

IMMUNOLOGY

Device: Reagent, Monoclonal
Manufacturer: The Binding Site Inc.
Brand: Free Lite Human Lambda Free Kit-olympus Au Series
Lot #: Lot# 257764A
Problem:

Upon receipt of a new lot of reagent (The Binding Site Ltd., San Diego, CA, Lot #257764A)for serum free light chain lambda, our method validation noted a shift between lots >40%. Free lambda chain results displayed clinically significant differences in 4 out of 5 patients as well as kappa/lambda ratio changes in 3 out of 5 patients.

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Manufacturer response for specific lot # of reagent, FREE LITE Human Lambda free kit-Olympus AU Series

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In an attempt to resolve the problem, the discrepant samples were also assayed by the manufacturer who reported the same discrepancies, but offered no solution to the problem. We suggested that the manufacturer inform other reagent users of the problem. Manufacturer indicated that the problem was unique to our lab.

OBSTETRICS/GYNECOLOGY

Device: Vacuum Assist Delivery System
Manufacturer: Cooper Surgical
Brand: M-style Mushroom Cup
Lot #: 60734
Other #: Ref # 10007LP

Problem:
After vacuum delivery, the cup did not easily release from infants head after pressure was released. Cup removed manually by physician. Small vacuum mark noted to infants head.

Device: Accessory, Colpotomy
Manufacturer: Cooper Surgical
Brand: Koh Colpotomizer System
Problem:
Recently a 72 year old female underwent a laparoscopic total hysterectomy with bilateral salpingo-oophorectomy and lysis of adhesions using an uterine manipulator injector system. Physicians had been trained in the use of the other system and were now trialing the Koh Colpotmizer System with two company representatives present in the OR. The procedure was uncomplicated and the patient was transferred to the recovery room in stable condition. The patient was discharged the day following surgery. Approximately 14 days later, she was seen by the attending surgeon for post-operative follow-up with no complaints. Approximately 3 weeks following, during a recheck with the attending surgeon, a vaginal exam was completed revealing a blue colored object present in the top of the vaginal vault. An unsuccessful attempt was made to remove the foreign body in the office. The patient was taken to surgery and given a spinal anesthesia with easy removal of the retained collar, a blue resin cup from the Koh Colpotomizer System. Vaginal exam appeared to be normal with minimal bleeding. The patient was discharged in stable condition when alert and awake. The patient is recovering without any residual side effects.

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HEMATOLOGY

Device: Analyzer, Coagulation, Whole Blood
Manufacturer: International Technidyne Corporation (ITC)
Brand: Hemochron
Model #: Hemochron Signature Junior Plus
Problem:
All of the data we analyzed had been collected by the warfarin clinics for QA purposes. We obtained IRB (Institutional Review Board) approval for our analysis. We conducted an analysis of 1,666 paired INR samples (venous sample and point of care device from the same patients at the same time) over the course of 2.5 years. The device did not report the following INR values: 2.1, 3.1, 3.8, 4.1, and 4.4. INR values of 2.7 and 3.5 occurred once. There is not much evidence that it is a simple rounding issue, since values adjacent to the missing values do not appear to be systematically over-represented. Additionally, the value 2.5 (the value at the middle of the most common target INR range) appears to be over-represented, accounting for over 8% of all values reported by the device. We have a general concern with the distribution of values from the device compared to our routine laboratory. The device tends to inflate INR values compared with the lab, especially at the low end of the INR scale. This could lead clinicians to believe the patient is within the target INR range when the laboratory INR would indicate the same patient is at significantly increased risk for a thromboembolic event.

PHYSICAL MEDICINE

Device: Bed, Air
Manufacturer: Kinetic Concepts, Inc
Brand: Kinair Medsurg Specialty Bed
Model #: Kin Air MedSurg-40030A

Problem:
During the early morning, a patient was found on the floor. Patient is a PARA. He stated that he went to move to the right side and all of a sudden the bed deflated (specialty bed), and he slid between the rail with his lower extremities first. He had a pillow under his bottom and two behind his back when he was found. No breakdown or any signs of harm. VSS. The ceiling lift was used to get him into the recliner. MD paged and wife called. Apparently this bed had been reported earlier. Biomed came earlier to fix this bed and was unable to. Patient stated they were going to send another person to fix it. Unable to get the bed to re-inflate or do anything, so the bed was reported again. Obtained a regular bed for the remainder of the night. Patient remains stable and unharmed as of now. Will continue frequent assessment.
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Manufacturer response for Bed, Kin Air MedSurg, Bed, Kin Air MedSurg
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KCI tested the bed yesterday and there is a problem with the up-down button on the side-rail, however we could not duplicate the mattress deflation problem. It is possible that

when the patient was trying to move to his right side he accidentally pushed the CPR button which deflates the mattress (the bed came to us with CPR button pushed to "ON". The bed is plugged in and inflation function is working properly.

Device: Stimulator, Neuromuscular, Therapeutic
Manufacturer: Chattanooga Group
Brand: Vectra Genisys
Model #: 2872

Problem:
Vectra Genisys neuromuscular stimulator was being used on patient. The patient initially felt a normal wave pattern on the Left side but nothing on the Right. The sensation then went away completely, but returned on the Right side. He said his side felt like he had been hit by lightning. The shock came just on the Right side between the electrodes. The patient yelled out and said the shock was intense enough to make him jump up. Physical Therapy Assistant shut it off immediately and asked Physical Therapist to come to see the pt. Patient was given juice and crackers. PT went to check with patient after the event. He was in a panic and stated that he felt a shock and was worried about his heart and physical reaction to follow. Assured patient we were medically trained to take care of his needs, had an AED and would call for any supportive help if needed.

Biomed tested the stimulator and accessories. A set of stimulator wires that attach the device to the electrodes was found to have an intermittent connection near the plug. It is very possible that the intensity to the generator was turned up because the patient didn't feel anything when the wires were not conducting. When the wires were flexed and conducting, the intensity knob could have been set much higher than what the patient needed, causing "shock-like" feeling. The bad lead set was disposed of and a new set is being ordered. Informed PT supervisor of findings.

CARDIOVASCULAR

Device 1: Cannulas, Ecmo, Venous
Manufacturer: Medtronic Perfusion Systems
Lot #: V: 2006110346
Cat #: 96830-008

Device 2: Cannula, Ecmo, Arterial
Manuf: Medtronic Perfusion Systems
Lot #: A: 2008021026
Cat #: 96820-008

Problem:
Patient was being cannulated for Venous/Arterial extra corporeal membrane oxygenation. Surgeons cannulated the vein with the arterial catheter, and the artery with the vein catheter. The cannulas (side by side with trocar in the venous catheter) look identical.

There are no markings (ex. blue/red bands) to distinguish between the catheters.

Device: Oxygenator, Membrane
Manufacturer: Cobe Cardiovascular, Inc.
Brand: Apex
Model #: Apex
Lot #: 209598-0221
Problem:
Increasing levels of CO2 noted during procedure. Equipment was checked and a crack was noted in the oxygenator housing. The piece was replaced. A gas sweep of 11 liters/min started to drop patient's blood CO2 levels to near normal. The remaining inventory of were checked and other unit were found to be cracked. Other damaged inventory removed from stock.

Device: Sheath, Iv
Manufacturer: Bard Electrophysiology
Brand: Bard (Sheath W/valve And Sideport)
Lot #: S25589
Cat #: 808700

Problem:
While preparing for placement of a pacemaker, a 7f sheath by Bard was being set up. A guidewire must pass through an 18g needle to access the vessel. The problem was, the wire would not pass through the needle. We attempted this procedure with three different packages and none of the three were successful. Finally a fourth kit was used and was successful. No injury to pt.

Device: Electrode, Defibrillation/external Pacing
Manufacturer: Covidien LP
Brand: Medi-trace Cadence Multifunction Radiotransparent Electrode
Model #: Adult and Pediatric electrodes were involved
Lot #: 631467; 728509; 632613
Cat #: 22770R

Problem:
Pediatric patient receiving CPR. Multi-function defibrillator pads when separated from the plastic protective liner, left the gel material adhering to the plastic liner. Gel material did not remain attached to the actual electrode. Multiple packages were opened and checked, and several were faulty. Most packages had 2008 expiration dates, but some had 2009 and 2010. All remaining expiration 2008 pads removed from patient care areas and replaced with packages with later expiration dates. Materials Management personnel will contact manufacturer and request replacement for all product with 2008 expiration dates. Materials Management Manger also stated that warehouse area where product is stored is maintained within recommended temperatures. All patient care areas are also maintained within recommended temperature range.

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Device: Catheter, Percutaneous
Manufacturer: Cordis
Brand: Lumend Outback
Cat #: OTB42120

Problem:
Risk Management received notification about a possible complication related to the use of a catheter this summer. Risk management contacted the surgeon who relayed at the time of incident he did not note a malfunction, and that he does not feel the device was misused in any way. However, the patient did develop a pseudoaneurysm within 12 hours of the procedure, developed bleeding and hypovolemic shock, and was emergently returned to the operating room. The patient did suffer a retroperitoneal bleed due to a perforated aorta at the level of iliac stenting. The surgeon notes in speaking with his peers at a cardiovascular conference that he was informed other surgeons had experienced similar consequences with this catheter, and in fact, the manufacturer had recently distributed a recall relating to this device. Risk management did determine a recall was received from the manufacturer, although not in our office. The manufacturer worked directly with our Cath Lab to remove devices this fall. The patient's surgery was prior to the recall. The recall relates to ALL lots of this product so it is felt the catheter utilized in the event was involved with this recall.
Please see recall on this device online available at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?ID=73246

GENERAL & PLASTIC SURGERY

Device: Forceps, Dissecting, Robotic Surgical
Manufacturer: Intuitive Surgical, Inc.
Brand: Da Vinci Endowrist Cadiere Forceps
Model #: 420049 ver-05
Lot #: S10080603083

Problem:
During surgical procedure a splinter size piece of graphite material was noted in the patient's abdomen. It was apparent that the piece broke free from the robotic wristed instrument. This happened during the removal and insertion of the instrument from the robot arm. Doctor was aware and indicated that it would not have any adverse effect on the patient.
Intuitive Surgical has since provided the hospital with an inspection procedure for our 8mm cannulae, which involves a visual inspection and the use of a "gage pin", also provided by Intuitive Surgical. The procedure is recommended to be performed prior to sterilization and prior to surgery to detect damaged cannulae.

Device: Esu, Shears Cover, Robotic
Manufacturer: Intuitive Surgical, Inc.
Brand: Da Vinci

Model #: 400180-05
Lot #: C8184

Problem:
During robotic surgical procedure for Total laparoscopic hysterectomy, approximately one hour into surgery, device arc occurred and arc hit uterine tissue. Hysterectomy in progress and no harm to patient.

Tip cover accessory being used with the monopolar curved shears Da Vinci surgical System by Intuitive. Arc occurred during use resulting in tip cover accessory on device noted to have brown spots and holes after arc of shears occurred.

Machine at recommended settings and tip cover applied to monopolar shears according to manufacturer's direction.

Device: Laser, Holmium, Urological
Manufacturer: American Medical Systems, Inc.
Brand: Stonelight

Problem:
Laser machine failed to operate properly. When foot pedal was initiated it worked well and suddenly stopped working. Procedure terminated with arrangements for follow up wave lithotripsy.

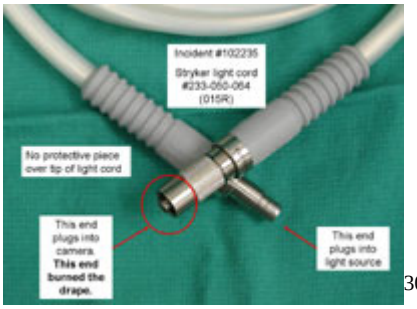
Biomedical Engineering Assessment of Problem: Laser failed to function during case. Contracted equipment owner/operator identified problem as the foot switch cable. Recommendation: Connector on the footswitch cable (where it connects to the laser) was damaged. Biomed had done a safety inspection of the laser prior to the case, but the damaged connector was not seen. It is the vendor's responsibility to check the functionality of their equipment prior to a case.

GASTROENTEROLOGY & UROLOGY

Device: Cord, Fiber Optic Light
Manufacturer: Karl Storz Endoscopy-America, Inc.
Model #: 495ND

Problem:
There are different light cords for endoscopic cases. The tips of the light cords can project past the sheath that screws into the scopes. When the scope is disconnected, it is human nature to set the cord down for a short while. This is not good in general, but when the tip is not protected, it can cause a burn to whatever it touches (it may be 500+ degrees), usually the drapes. If there was oxygen nearby, there is potential for a fire. This has happened on multiple occasions. We have asked to have all of these light cords removed. I understand that some surgeons prefer these cords, so they are used occasionally. Hence,

the fire today. The blue drape and the patients blanket had a hole/burn on them. If the patient was closer, the patients skin would have been burned as well.



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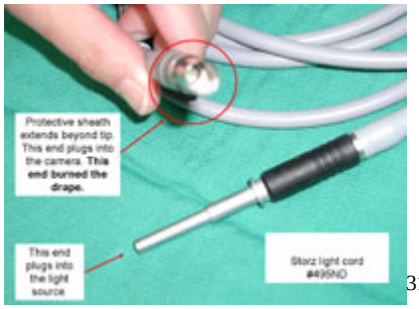

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Device: Separator, Automated, Blood Cell And Plasma, Therapeutic
Manufacturer: Gambro BCT, Inc.
Brand: Spectra Apheresis System
Problem:
"Spectra Apheresis System was repaired by Gambro Equipment Service Technician. Repair was replacement of cracked centrifuge housing. Equipment was used properly the following day. At start of procedure (approx 09:25) equipment alarmed, indicating blood spill in centrifuge chamber. Tubing in Centrifuge Chamber was broken, causing blood leakage. Procedure terminated. Patient, on ECMO Circuit, experienced a minimal (50 - 100 ML) blood loss. No other patient harm occurred. Upon examining equipment, two tabs were noted in the horizontal round opening of the Centrifuge Housing. These tabs are not on the other, identical, apheresis machines. It appears that one of these tabs had contact with the tubing and the friction that occurred with the movement of the tubing within the centrifuge caused the tubing to break. No further treatment of the patient related to this incident was required. The patient underwent the ordered apheresis procedure with another apheresis machine.
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Manufacturer response for Spectra Apheresis System, Spectra Apheresis System
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Manufacturing issue the two tabs were noted in the horizontal round opening of the Centrifuge Housing. These tabs are not on the other, identical, apheresis machines. It appears that one of these tabs had contact with the tubing and the friction that occurred with the movement of the tubing within the centrifuge caused the tubing to break.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With the ConMed VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator) Uterine Manipulator

Print Item
E–mail Item

MedSun Newsletter #32, January 2009

Over the past four months, MedSun has received nine adverse event reports associated with the VCARE device manufactured by ConMed Corporation, which resulted in a recall. The reports were submitted by three different hospitals between April 2008 and July 2008. The reported device problems include:

•Three balloon failures, with two of these reports also including retained portions of the device.
•Two cup malfunctions; one report of the cup breaking into pieces, and one report of the cup melting during the procedure.
•Two reports of the device breaking into pieces after placement.
•Two reports of the device resulting in uterine perforations.

The reported patient injuries include:

•One report of the retained portion of device removed in the physician's office.
•One report of the retained portion of device resulting in pain and malodorous odor, with the patient admitted to the hospital for prophylactic antibiotic treatment.
•Two reports of uterine perforations; however, these patients were scheduled for laparoscopic hysterectomies. One case was converted to an open abdominal procedure.

The reported female patient age range was 34 years to 56 years old.

These MedSun reports contributed to FDA awareness of the device problems. FDA follow-up with the manufacturer resulted in a Class II Recall. The following recall, describing problems with the VCARE, are noted to be associated with the ConMed device.

On October 28, 2008, the VCARE was voluntarily recalled by the manufacturer because the firm received several complaints sighting detachment of the balloon at the distal end of the shaft. It was also noted that the incidence of the forward cup slipping off the shaft and being retained in the vaginal canal had increased.

Summary of MedSun Reports Describing Adverse Events With the ConMed VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator) Uterine Manipulator

Device	Device Identifiers	Event Description
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Catalog # 60-6085-100 Lot # 0803121 Standard	Surgeon had to manually extract V-care cup from the cervical os. Patient remained stable; no issues related to removing manipulator.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-	Ref # 60-6085-100 Lot # 0803061	V-Care manipulator broke into pieces after procedure. The entire device was accounted for post-procedure. No Patient Harm. We have had

Elevator)	Standard	prior problems with this device, and recently received additional in-service training from the manufacturer. During the training we did not identify any procedural issues that would explain the failures.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Device Identifiers Unknown	The cup which was inserted into the cervix melted during the surgery. The physician stated that there was no harm to the patient as a result of this incident. A follow up in-service with the staff will take place regarding the operation of the ESU device.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Device Identifiers Unknown	As the doctor was blowing up the balloon during removal of the device, it broke into pieces. There was no patient harm as a result of this incident.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Model # 60-6085	While manipulating the uterus with the device, the balloon failed and this may have caused the device to come apart and the cervical cap to remain in the patient.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Ref#60-6085-102 Lot # 0803111 Large	The tip of the balloon broke off and the end piece that is bell shaped remained attached and remained in the cervix. This was not noticed by the surgical team. Patient was seen in the surgeon's office 10 days following surgery and the piece of the device was discovered. The patient had been experiencing pain and malodorous odor. The surgeon admitted her to another hospital, other than where the surgery was performed, for prophylactic antibiotics. The patient is doing well at this time.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Ref# 60-6085-100 Lot # 0801281 Standard	During a laparoscopic robotic assisted procedure, the VCARE broke down in parts into the patient's uterus. The physician scrubbed in, removed the uterus and all of the remaining parts of the VCARE (Uterine manipulator) through the vagina. No additional intervention was needed at the time.
ConMed/VCARE (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)	Serial # 606085101 Lot # 0801281 Small	VCare perforated uterus during robotic-assisted (using the daVinci system) laparoscopic-assisted vaginal hysterectomy with BSO (bilateral salpingo oopherectomy).
ConMed/VCARE (Vaginal-Cervical-	Ref # 60-6085-100 Lot #	Patient was scheduled to have a laparoscopic hysterectomy, appendectomy, and right

Ahluwalia's-Retractor-Elevator)	0801281 Standard	salpingo oophorectomy. The physician initially placed the uterine manipulator via vagina (V Care Standard Size). When the laparoscopic procedure started, the surgery team discovered that the manipulator had perforated the uterus.